For: NUCLEIC ACID ENCODING SPINOCEREBELLAR ATAXIA-2 AND PRODUCTS RELATED THERETO

#### Remarks

The Office Action mailed December 5, 2001 has been received and reviewed. Claims 6 and 62-70 having been canceled, claims 1, 5, and 74 having been amended, and claims 76-84 having been added, the pending claims are claims 1-3, 5, 7, 59, 61, and 71-84. Reconsideration and withdrawal of the rejections are respectfully requested

The amendments to claim 1 are supported by the specification at, for instance, page 10, lines 22-27; page 15, lines 29-35; page 31, lines 7-17; page 32, lines 17-22; and page 47, line 26-28.

The amendments to claim 5 are supported by the specification at, for instance, page 13, line 26 through page 14, line 3.

New claims 76 and 77 are supported by the specification at, for instance, page 20, line 7 through page 21, line 2.

New claims 78 and 79 are supported by the specification at, for instance, page 20 lines 6-25.

New claims 80 and 81 are supported by the specification at, for instance, page 44, lines 1-9. The sequence identifier numbers recited in claims 80 and 81 were added to the specification in the Preliminary Amendment mailed July 5, 1999.

New claim 82 is supported by the specification at, for instance, page 13, line 26 through page 14, line 3.

New claims 83 and 84 are supported by originally filed claim 7, and by the specification at, for instance, page 18, line 33 through page 19, line 4.

#### **Information Disclosure Statement**

The Examiner is respectfully requested to note that Applicants submitted an Information Disclosure Statement and form PTO-1449 on November 14, 2001 (copy enclosed). The postcard sent with the Information Disclosure Statement was returned, and stamped as

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received by the PTO January 2, 2001 (copy enclosed); however, it does not appear that the document cited on the form PTO-1449 was considered by the Exmainer.

An Information Disclosure Statement shall be considered by the Office if it is filed before the mailing date of a first Office Action on the merits. 37 C.F.R. § 1.97(b)(3). The enclosed copy of the Information Disclosure Statement and form PTO-1449 were filed before the mailing date of a first Office Action on the merits. Consequently, the Examiner is requested to consider the document cited on the Information Disclosure Statement submitted November 14, 2001. A copy of the document, Tsuji et al. (U.S. Patent 6,251,589) is included for the convenience of the Examiner.

## The 35 U.S.C. §112, First Paragraph, Rejection

The Examiner rejected claims 6 and 69 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed. In the interests of furthering prosecution, claims 6 and 69 have been cancelled, thereby rendering the rejection moot.

# The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 1-3, 5-7, 62-70, and 74 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 65-70 have been canceled. This rejection, as it relates to the pending claims, is respectfully traversed.

Claims 1-3 were rejected as indefinite over the recitation "an SCA2 polypeptide." Claims 1-3 as amended do not recite "an SCA2 polypeptide." Thus, the rejection of claims 1-3 is rendered moot.

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Claims 1-3 were rejected as indefinite "because it is unclear whether the nucleic acid must encode a full length SCA2 polypeptide or rather any part of the SCA2 polypeptide of SEQ ID NO:1-5." Claim 1 has been amended to recite "wherein the nucleic acid comprises an open reading frame of greater than 140.1 kDa," thus a person of ordinary skill would recognize that a nucleic acid of claim 1 would encode a full length SCA2 polypeptide.

Claim 5 was rejected over the recitation "high stringency." Claim 5 has been amended to no longer recite "high stringency." Thus, the rejection of claim 5 is rendered moot.

Claim 74 was rejected as indefinite "because it is unclear what the scope of the claim requires." Claim 74 has been amended to recite "an isolated nucleic acid comprising a nucleotide sequence set forth at SEQ ID NO:19." Thus, the rejection of claim 74 is rendered moot.

## The 35 U.S.C. §102 Rejection

The Examiner rejected claims 1-2, 5, 62, and 64 under 35 U.S.C. §102(b) as being anticipated by Sanpei et al. (Biochemical and Biophysical Research Communications, 212, 341-346, July 1995), and claims 1-2 and 65-66 under 35 U.S.C. §102(e) as being anticipated by Brennan (U.S. Patent No. 5,474,796). Claims 62 and 64-66 have been canceled. This rejection, as it relates to the pending claims, is respectfully traversed.

To anticipate a claim, the document must teach every element of the claim. It is respectfully submitted that neither Sanpei et al. nor Brennan teach every element of the pending claims. Sanpei et al. disclose a method for the direct detection of expanded (CAG/CTG) repeats in the myotonin-protein kinase genes of myotonic dystrophy patients using a high-stringency hybridization method that includes using a single-stranded probe containing (CAG)<sub>55</sub>. Brennan discloses a method for the assembly of oligonucleotides having 10 nucleotides on an array. Sanpei et al. and Brennan do not disclose, for instance, isolated nucleic acid obtained from locus q24.1 of chromosome 12 (claim 1) or isolated nucleic acid, wherein the nucleic acid encodes a polypeptide of SEQ ID NO:3 (claim 5).

**Amendment and Response** 

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Since neither Sanpei et al. nor Brennan teach every element of the pending claims, Sanpei et al. and Brennan do not anticipate the pending claims. Accordingly, the Examiner is requested to reconsider and withdraw the rejection of claims 1-2 and 5 under 35 U.S.C. §102(b) as being anticipated by the cited documents.

#### **Summary**

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

> Respectfully submitted for Stefan M. Pulst

By

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CERTIFICATE UNDER 37 CFR §1.10:

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The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to the Assistant

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By: Name:

Provence

# PPENDIX A - SPECIFICATION/CLAIM AMENDMENTS ELUDING NOTATIONS TO INDICATE CHANGES MADE

Serial No.: 08/981,998 Docket No.: 256.00010120

Amendments to the following are indicated by underlining what has been added and bracketing what has been deleted. Additionally, all amendments have been shaded.

#### In the Claims

For the Examiner's convenience, all of the pending claims are shown below.

- 1. (Three Times Amended) Isolated [human] nucleic acid [encoding an SCA2 polypeptide] obtained from locus q24.1 of chromosome 12 of a human with symptoms of spinocerebellar ataxia, wherein the nucleic acid comprises an open reading frame encoding a polypeptide of greater than 140.1 kDa and a CAG repeat region comprising at least 35 repeats encoding a polyglutamine tract, or a recombinantly produced nucleic acid having the nucleotide sequence of the isolated nucleic acid.
- 2. Isolated nucleic acid according to claim 1, wherein said nucleic acid comprises DNA.
  - 3. DNA according to claim 2, wherein said DNA is cDNA.
- 5. (Twice Amended) Isolated nucleic acid [DNA according to claim 2], wherein a complement of said nucleic acid [DNA] hybridizes [under high stringency conditions] to [the SCA2 coding portion of nucleotides 1 516 of SEQ ID NO:1 or nucleotides 163-4098 of SEQ ID NO:2 in a solution containing 50% formamide, 5X Denhardt's solution, 5% SSPE, 0.2% SDS at 42°C, followed by washing in 0.2X SSPE, 0.2% SDS at 65°C, wherein the DNA encodes a polypeptide of SEQ ID NO:3.
  - 7. A vector comprising DNA according to claim 2.
- 59. An isolated nucleic acid encoding the amino acid sequence set forth at SEQ ID NO:5.
- 61. An isolated nucleic acid set forth at SEQ ID NO:4 encoding an SCA2 polypeptide.
  - 71. An isolated nucleic acid comprising nucleotides 163-4098 of SEQ ID NO:2.
- 72. An isolated nucleic acid encoding the amino acid sequence set forth at SEQ ID NO:3.
  - 73. An isolated nucleic acid comprising nucleotides 50-3454 of SEQ ID NO:4.

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- 74. (Amended) An isolated nucleic acid <u>comprising a nucleotide sequence</u> set forth at SEQ ID NO:19.
- 75. An isolated nucleic acid comprising the nucleic acid sequence set forth at SEQ ID NO:19.
- 76. (New) An isolated nucleic acid comprising nucleotides 163-657 of SEQ ID NO:2.
- 77. (New) An isolated nucleic acid comprising nucleotides 724-4098 of SEQ ID NO:2.
- 78. (New) An isolated nucleic acid consisting of at least about 15 contiguous nucleotides from nucleotides 163-657 of SEQ ID NO:2, and the nucleotides complimentary thereto.
- 79. (New) An isolated nucleic acid consisting of at least about 15 contiguous nucleotides from nucleotides 724-4098 of SEQ ID NO:2, and the nucleotides complimentary thereto.
  - 80. (New) An isolated nucleic acid consisting of SEQ ID NO:6.
  - 81. (New) An isolated nucleic acid consisting of SEQ ID NO:7.
- 82. (New) Isolated nucleic acid, wherein a complement of said nucleic acid hybridizes to nucleotides 50-3454 of SEQ ID NO:4 in a solution containing 50% formamide, 5X Denhardt's solution, 5% SSPE, 0.2% SDS at 42°C, followed by washing in 0.2X SSPE, 0.2% SDS at 65°C, wherein the DNA encodes a polypeptide of SEQ ID NO:5.

## Amendment and Response - Appendix A

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83. (New) A vector comprising DNA according to claim 5.

84. (New) A vector comprising DNA according to claim 82.